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17 UNITED STATES DISTRICT COURT
18 DISTRICT OF CALIFORNIA

19 ADRIANN GEORGES,

20 Plaintiff,

21 vs.

22 NOVARTIS PHARMACEUTICALS
23 CORP., et al.,

24 Defendants.

Case No. 2:06-cv-5207-SJO-VBK

PRE TRIAL CONFERENCE ORDER

Pre-Trial Conf: March 18, 2013
Time: 9:00 a.m.
Courtroom: 1
Judge: Hon. S. James Otero

Trial Date: April 2, 2013

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FINAL PRETRIAL CONFERENCE ORDER

Following pretrial proceedings, pursuant to Fed. R. Civ. P. 16 and L.R. 16,
IT IS ORDERED:

1. PARTIES

The parties are: Plaintiff Adriann Georges ("Plaintiff" or "Mrs. Georges") and Defendant Novartis Pharmaceuticals Corporation ("Defendant" or "NPC").

Each of these parties has been served and has appeared. All other parties named in the pleadings and not identified in the preceding paragraph are now dismissed.

The pleadings which raise the issues are: Plaintiff's Complaint; Defendant's Answer to Plaintiff's Complaint; Order on Defendant's Motion for Summary Judgment (Dkt. No. 189); Order on Defendant's Daubert Motions to Exclude Expert Testimony (Dkt. No. 188).

2. JURISDICTION AND VENUE

Federal jurisdiction and venue are invoked upon the grounds:

- Jurisdiction is appropriate pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$ 75,000.00.
- Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)(1) and 1391(b)(2) because Plaintiff resides within this judicial district, and because a substantial part of the events and omissions giving rise to the claims occurred within this judicial district.
- The facts requisite to federal jurisdiction are admitted.

3. TRIAL ESTIMATE

Mrs. Georges' Position

Plaintiffs estimate the trial will take approximately 12 days including openings and

1 closings. Plaintiff also estimates that plaintiff's case will taken 6 to 7 court days, while
2 defendant's case will take approximately 3 to 4 court days. These estimates are based on
3 the 10 trials that have previously taken place, most of which Mr. Vecchione has been
4 involved with. Twelve court days will allow sufficient time to present the issues in this
5 case, some of which are scientific and more complex in nature. That being said, plaintiff
6 will strive to cut as much from her trial presentation as possible and narrowly focus her
7 evidence to the time period relevant to this case.

8 Defendant prefers that the parties each be given 15 hours to present their case.
9 However, plaintiff's case has always taken longer than defense's, and plaintiff will be
10 unfairly burdened if she is held to the same allocation of time as the defendant. Further,
11 many documents that Defendant objects to are admitted through taped testimony of its
12 employees and former employees. These tapes could be cut shorter if the objections to
13 documents were removed.

14 NPC's Position

15 The Court informed the parties at the November 28, 2012, mediation that each side
16 will be allowed 15 hours to present its case, exclusive of time spent in *voir dire*, opening
17 statements, and closing arguments. NPC has relied on this clear statement by the Court in
18 preparing and structuring its defense for trial, and will be prejudiced if this rule is not
19 enforced. Plaintiff's late attempts to circumvent the Court's time limitations should be
20 denied.

21 Assuming each party's case will be limited to 15 hours, NPC believes that *voir dire*,
22 opening statements, the party's presentation of evidence, closing arguments, and jury
23 deliberations can all be completed within 10 court days.

24 25 **4. JURY TRIAL**

26 The trial is to be a jury trial. At least seven (7) days prior to the trial date the parties
27 shall file and serve by e-mail, fax, or personal delivery: (a) proposed jury instructions as
28 required by L.R. 51-1 and (b) any special questions requested to be asked on *voir dire*.

1
2 **5. STIPULATED FACTS DEEMED ADMITTED**

3 The following facts are admitted and require no proof:

4 On March 1, 2013, NPC supplied a proposed list of stipulated facts to be deemed
5 admitted, based largely on Plaintiff's Statement of Uncontroverted Facts (ECF No. 96), on
6 facts Plaintiff did not dispute in Plaintiff's Response to Defendant's Statement of
7 Uncontroverted Facts (ECF No. 95), and on facts stated in the Court's Order Denying
8 Defendant's Motion for Summary Judgment (ECF No. 189). As of this time, the parties
9 have been unable to come to an agreement regarding these proposed stipulated facts.
10 However, negotiations are ongoing, and the parties are hopeful that they can reach an
11 agreement by the time of the pre trial conference. If the parties reach agreement, they will
12 file an amended Pre Trial Conference Order prior to the pre trial conference.

13
14 **6. STIPULATED FACTS NOT ADMITTED**

15 On March 9, 2013, NPC supplied a proposed list of stipulated facts without
16 prejudice to evidentiary objections. This list contained many of the same facts listed in
17 NPC's original proposed list of stipulated facts, referenced in paragraph 5. As of this time,
18 the parties have been unable to come to an agreement regarding these proposed stipulated
19 facts. However, negotiations are ongoing, and the parties are hopeful that they can reach
20 an agreement by the time of the pre trial conference. If the parties reach agreement, they
21 will file an amended Pre Trial Conference Order prior to the pre trial conference.

22
23 **7. CLAIMS AND DEFENSES**

24
25 PLAINTIFF'S CLAIMS

- 26
27 (a) Plaintiffs plan to pursue the following claims against the following defendants:
28
 - Claim 1: Product Liability – Strict Liability;

- Claim 2: Negligence – Negligent Manufacturing and Failure to Warn;
- Claim 3: Breach of Warranty; and
- Claim 4: Fraudulent Concealment

(b) The elements required to establish Plaintiff's claims are:

Claim 1: Product Liability – Strict Liability

1. That NPC manufactured, distributed or sold Aredia and Zometa;
2. That Aredia or Zometa had potential risks or side effects that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community at the time of manufacture, distribution or sale;
3. That the potential risks or side effects presented a substantial danger when Aredia or Zometa are used or misused in an intended or reasonably foreseeable way;
4. That ordinary consumers would not have recognized the potential risks or side effects;
5. That NPC failed to adequately warn or instruct of the potential risks or side effects;
6. That Mrs. Georges was harmed;
7. That the lack of sufficient instructions or warnings was a substantial factor in causing Mrs. Georges' harm;
8. The warning must be given to [Mrs. Georges'] prescribing physician and must include the potential risks, side effects, or allergic reactions that may follow the foreseeable use of Aredia and Zometa. NPC had a continuing duty to warn physicians as long as the Aredia and Zometa were in use.

See CACI §1205.

Defendant objects to Plaintiff's characterization of the elements for this claim, and in response, contends that the elements should read as follows:

- 1) That Novartis manufactured and distributed Aredia® and Zometa®;
- 2) That Aredia® and Zometa® had potential risks that were known or reasonably

1 scientifically knowable in light of the scientific and medical knowledge that was
2 generally accepted in the scientific community at the time of distribution;

3 3) That the potential risks presented a substantial danger when Aredia® or Zometa®
4 are used or misused in an intended or reasonably foreseeable way;

5 4) That prescribing physicians would not have recognized the potential risks;

6 5) That after it became known or reasonably scientifically knowable that Aredia® and
7 Zometa® had potential risks, NPC failed to adequately warn Ms. Georges'
8 prescribing physician, Dr. James Waisman, of the potential risks;

9 6) That Ms. Georges was harmed; and

10 7) That lack of sufficient warnings to Dr. Waisman was a substantial factor in causing
11 Ms. Georges' harm.

12 The warning must be given to the prescribing physician and must include the
13 potential risks, side effects, or allergic reactions that may follow the foreseeable use of the
14 product. NPC had a continuing duty to warn prescribing physicians as long as the product
15 was in use.¹

16
17 **Claim 2: Negligence – Negligent Manufacturing and Failure to Warn**

18 1. That NPC manufactured, distributed or sold Aredia and Zometa;

19 2. That NPC knew or reasonably should have known that Aredia or Zometa were
20 dangerous or were likely to be dangerous when used in a reasonably foreseeable manner;

21 3. That NPC knew or reasonably should have known that users would not realize
22 the danger;

23 4. That NPC failed to adequately warn of the danger or instruct on the safe use
24 of Aredia or Zometa;

25
26 ¹ CACI Jury Instruction No. 1222 (modified in accordance with applicable case law, to incorporate learned
27 intermediary doctrine, and to fit the facts of this case); *Brown v. Superior Court*, 44 Cal.3d 1049, 1069, 245
28 Cal. Rptr. 412, 424 (Cal. 1988) (drugs must be accompanied by warnings of "dangerous propensities that
were either known or reasonably scientifically knowable at the time of distribution.").

1 5. That a reasonable manufacturer, distributor or seller under the same or similar
2 circumstances would have warned of the danger or instructed on the safe use of Aredia or
3 Zometa;

4 6. That Mrs. Georges was harmed;

5 7. That NPC's failure to warn or instruct was a substantial factor in causing Mrs.
6 Georges' harm; and

7 8. The warning must be given to Mrs. Georges' prescribing physician and must
8 include the potential risks or side effects that may follow the foreseeable use of Aredia or
9 Zometa. NPC had a continuing duty to warn physicians as long as Aredia or Zometa were
10 in use.

11 *See* CACI §1222.

12 Defendant objects to Plaintiff's characterization of the elements for this claim, and in
13 response, contends that the elements should read as noted below. Defendant additionally
14 objects to the characterization of this claim as a "Negligent Manufacturing and Failure to
15 Warn" claim, as it is only a failure to warn claim.

16 1) That Novartis manufactured Aredia® and Zometa®;

17 2) That Novartis knew or reasonably should have known that Aredia® and Zometa®
18 were dangerous or were likely to be dangerous when used or misused in a
19 reasonably foreseeable manner;

20 3) That Novartis knew or reasonably should have known that prescribing physicians
21 would not realize the danger;

22 4) That Novartis failed to adequately warn Ms. Georges' prescribing physician, Dr.
23 James Waisman, of the danger;

24 5) That a reasonable manufacturer under the same or similar circumstances would have
25 warned Dr. Waisman of the danger;

26 6) That Ms. Georges was harmed; and

27 7) That Novartis' failure to warn Dr. Waisman was a substantial factor in causing Ms.
28 Georges' harm.

1 The warning must be given to the prescribing physician and must include the
2 potential risks, side effects, or allergic reactions that may follow the foreseeable use of the
3 product. Novartis had a continuing duty to warn prescribing physicians as long as the
4 product was in use.²

5
6 **Claim 3: Breach of Warranty**

- 7 1. That Mrs. Georges bought the Aredia or Zometa from NPC
8 2. That, at the time of purchase, NPC was in the business of selling Aredia or
9 Zometa;
10 3. That the Aredia or Zometa was not fit for the ordinary purposes for which
11 such goods are used, were not adequately contained, packaged and labeled as the
12 agreement may require or did not conform to the promises or affirmations of fact made on
13 the container or label if any;
14 4. That Mrs. Georges took reasonable steps to notify NPC within a reasonable
15 time that the product did not have the expected quality;
16 5. That Mrs. Georges was harmed; and
17 6. That the failure of Aredia or Zometa to have the expected quality was a
18 substantial factor in causing Mrs. Georges' harm.

19 *See* CACI §1231; *see also* California Commercial Code Sec. 2314.

20 Defendant objects to Plaintiff's claim for Breach of Warranty in its entirety.³
21 Plaintiff is not entitled to an instruction for Breach of Warranty because an implied
22 warranty claim is "obviously . . . incompatible with . . . the scope of a drug manufacturer's
23 liability for product defects." *Brown v. Superior Court*, 44 Cal. 3d 1049, 1072, 245 Cal.

24
25 ² CACI Jury Instruction No. 1222 (modified in accordance with applicable case law, to incorporate learned
26 intermediary doctrine, and to fit the facts of this case); *Brown v. Superior Court*, 44 Cal.3d 1049, 1069, 245
27 Cal. Rptr. 412, 426 (1988) (drugs must be accompanied by warnings of "dangerous propensities that were
28 either known or reasonably scientifically knowable at the time of distribution.").

³ Plaintiff's Breach of Warranty claim is based only on an implied warranty theory. Plaintiff has not
alleged a breach of express warranty claim.

1 Rptr. 412, 426 (1988). Moreover, Ms. Georges was not in privity with Novartis, and Ms.
2 Georges relied solely on her prescribing physician to prescribe the appropriate drugs. *See*
3 *Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058-1059, 70 Cal. Rptr. 3d
4 566, 582 (Cal. Ct. App. 2008); *Evraets v. Intermedics Intraocular, Inc.*, 29 Cal.App.4th
5 779, 784, 34 Cal. Rptr. 2d 852 (Cal. Ct. App. 1994); *United States Roofing, Inc. v. Credit*
6 *Alliance Corp.*, 228 Cal. App. 3d 1431, 1441, 279 Cal. Rptr. 533 (Cal. Ct. App. 1991)
7 (“Vertical privity is a prerequisite in California for recovery on a theory of breach of the
8 implied warranties of fitness and merchantability.”).

9
10 **Claim 4: Fraudulent Concealment**

- 11 1. That NPC concealed or suppressed a material fact;
- 12 2. That NPC was under a duty to disclose the fact to Mrs. Georges;
- 13 3. That NPC intentionally concealed or suppressed the fact with the intent to
14 defraud Mrs. Georges;
- 15 4. That Mrs. Georges was unaware of the fact and would not have acted as she
16 did if she had known of the concealed or suppressed fact; and
- 17 5. That as a result of the concealment or suppression of the fact, Mrs. Georges
18 sustained damage.

19 *Jones v. ConocoPhillips Co.*, (2011) 198 Cal. App. 4th 1187, 1198.

20 Defendant objects to Plaintiff’s characterization of the elements for this claim, and in
21 response, contends that the elements should read as follows:

- 22 1) That Novartis intentionally failed to disclose an important fact that was known only
23 to Novartis and that Ms. Georges’ prescribing physician, Dr. James Waisman, could
24 not have discovered.
- 25 2) That Dr. Waisman did not know of the concealed fact;
- 26 3) That Novartis intended to deceive Dr. Waisman by concealing the fact;
- 27 4) That Dr. Waisman reasonably relied on Novartis’ deception;
- 28 5) That Ms. Georges was harmed; and

6) That Novartis' concealment was a substantial factor in causing Ms. Georges' harm.⁴

(c) The key evidence Plaintiff relies on for each of the claims is:

Claim 1: Product Liability – Strict Liability

1. That NPC manufactured, distributed or sold Aredia and Zometa;

- NPC does not contest that it sold and distributed Aredia® and Zometa®.

2. That Aredia or Zometa had potential risks or side effects that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community at the time of manufacture, distribution or sale;

- Live testimony of Robert Marx regarding the side effect or risk of ONJ and what was known or knowable at the time of manufacture, distribution or sale.
- In 1981, Dr. Jack Gotcher and Dr. W. S. S. Jee published an article explaining their findings in an experiment where rats were exposed to a bisphosphonate drug, clodronate. The experiment was performed to test the effect of clodronate on periodontal disease in the animals. Dr. Gotcher's and Dr. Jee's findings were startling. They saw exposed, devitalized (dead) bone protruding in the oral cavities of several of the rats treated with clodronate. None of the rats given the placebo experienced this condition. (See Exhibit 227).
- Marx textbook on ONJ. (See Exhibit 1031).
- Landesberg email to Dunsire regarding Ruggiero's 25 instances of ONJ.
- Fratarcangeli email regarding plan to suppress Ruggiero's article from ever seeing the light of day.
- Goessl email to NEM team regarding osteopetrosis.
- Document(s) evidencing cases of ONJ in the clinical trials.

⁴ CACI Jury Instruction No. 1901 (modified to incorporate the learned intermediary doctrine and to fit the facts of this case).

1
2 **3. That the potential risks or side effects presented a substantial danger**
3 **when the Aredia or Zometa are used or misused in an intended or reasonably**
4 **foreseeable way;**

- 5 • Live testimony of Robert Marx regarding the use of and substantial danger
6 posed by ONJ.
7 • Marx textbook on ONJ. (*See* Exhibit 1031).
8

9 **4. That ordinary consumers would not have recognized the potential risks**
10 **or side effects;**

- 11 • Live testimony of Robert Marx regarding risks and side effects.
12 • Live testimony of Mrs. Georges.
13 • Testimony of Dr. Radack.
14 • Testimony of Dr. Waisman.
15 • Testimony of Dr. Sung.
16 • Email of Linda Weiss regarding alternate risk factors.

17 **5. That NPC failed to adequately warn or instruct of the potential risks or**
18 **side effects;**

- 19 • Live testimony of Dr. Suzanne Parisian regarding warnings and instructions.
20 • Aredia and Zometa labels.
21 • Live testimony of Robert Marx regarding potential risks and side effects of
22 Aredia and Zometa.
23 • Fratacangeli email regarding plan to suppress Ruggiero's article from ever
24 seeing the light of day.
25 • Email from Dr. Ruggiero regarding ONJ cases.
26 • Email from Schubert regarding white paper.
27 • Email of Linda Weiss regarding alternate risk factors.
28

1 **6. That Mrs. Georges was harmed;**

- 2 • Live Testimony of Mrs. Georges.
- 3 • Live testimony of Mr. Georges.
- 4 • Live testimony and expert report of Dr. Sung.
- 5 • Testimony of Dr. Waisman.
- 6 • Mrs. Georges' medical records, and other documents and photographs
- 7 produced by plaintiff. (*See Exhibits*1116-1176, 1179, 1181).
- 8

9 **7. That the lack of sufficient instructions or warnings was a substantial**
10 **factor in causing Mrs. Georges' harm;**

- 11 • Live Testimony of Mrs. Georges.
- 12 • Live testimony of Mr. Georges.
- 13 • Testimony of Dr. Waisman and other treating physicians.
- 14 • Testimony of Dr. Radack.
- 15 • Live testimony of Dr. Sung.
- 16 • Mrs. Georges' medical records, and other documents and photographs
- 17 produced by plaintiff. (*See Exhibits*1116-1176, 1179, 1181).
- 18

19 **8. The warning must be given to [Mrs. Georges'] prescribing physician and**
20 **must include the potential risks, side effects, or allergic reactions that may follow the**
21 **foreseeable use of Aredia and Zometa. NPC had a continuing duty to warn**
22 **physicians as long as the Aredia and Zometa were in use.**

- 23 • Aredia and Zometa labels.
- 24 • Edge and Compass reports relating to Mrs. Georges.
- 25 • NPC advertising.
- 26 • Physician's Desk Reference.

27 *See CACI* §1205.

28

Claim 2: Negligence – Negligent Manufacturing and Failure to Warn

1. That NPC manufactured, distributed or sold Aredia and Zometa;

- NPC does not contest that it sold and distributed Aredia® and Zometa®.

2. That NPC knew or reasonably should have known that Aredia or Zometa were dangerous or were likely to be dangerous when used in a reasonably foreseeable manner;

- Live testimony of Robert Marx.
- Live testimony of Dr. Suzanne Parisian.
- Aredia and Zometa labels.
- Fratarcangeli email regarding plan to suppress Ruggiero's article from ever seeing the light of day.
- Email from Dr. Ruggiero regarding ONJ cases.
- Email from Schubert regarding white paper.
- Email of Linda Weiss regarding alternate risk factors.
- Goessl email to NEM team regarding osteopetrosis.
- Document(s) evidencing cases of ONJ in the clinical trials.
- In 1981, Dr. Jack Gotcher and Dr. W. S. S. Jee published an article explaining their findings in an experiment where rats were exposed to a bisphosphonate drug, clodronate. The experiment was performed to test the effect of clodronate on periodontal disease in the animals. Dr. Gotcher's and Dr. Jee's findings were startling. They saw exposed, devitalized (dead) bone protruding in the oral cavities of several of the rats treated with clodronate. None of the rats given the placebo experienced this condition. (See Exhibit 227).

3. That NPC knew or reasonably should have known that users would not realize the danger;

- Live testimony of Robert Marx.
- Live testimony of Dr. Suzanne Parisian.

- Aredia and Zometa labels.
- Fratarcangeli email regarding plan to suppress Ruggiero's article from ever seeing the light of day.
- Email from Dr. Ruggiero regarding the fact that Aredia and Zometa are the real culprit behind ONJ cases.
- Email from Schubert regarding white paper.
- Email of Linda Weiss regarding alternate risk factors.
- Goessl email to NEM team regarding osteopetrosis.
- Document(s) evidencing cases of ONJ in the clinical trials.

4. That NPC failed to adequately warn of the danger or instruct on the safe use of Aredia or Zometa;

- Aredia and Zometa labels.
- Edge and Compass reports relating to Mrs. Georges.
- NPC advertising.
- Physician's Desk Reference.

5. That a reasonable manufacturer, distributor or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of Aredia or Zometa;

- Live testimony of Dr. Suzanne Parisian regarding the behavior expected from a reasonable manufacturer, distributor or seller under the same or similar circumstances.
- Live testimony of Robert Marx.

6. That Mrs. Georges was harmed;

- Live Testimony of Mrs. Georges.
- Live testimony of Mr. Georges.

- Live testimony and expert report of Dr. Sung.
- Testimony of Dr. Waisman and other treating physicians.
- Mrs. Georges' medical records, and other documents and photographs produced by plaintiff. (See Exhibits 1116-1176, 1179, 1181).

7. That NPC's failure to warn or instruct was a substantial factor in causing Mrs. Georges' harm; and

- Live Testimony of Mrs. Georges.
- Live testimony of Mr. Georges.
- Live testimony and expert report of Dr. Sung.
- Live testimony of Robert Marx.

8. The warning must be given to Mrs. Georges' prescribing physician and must include the potential risks or side effects that may follow the foreseeable use of Aredia or Zometa. NPC had a continuing duty to warn physicians as long as Aredia or Zometa were in use.

- Aredia and Zometa labels.
- Edge and Compass reports relating to Mrs. Georges.
- NPC advertising.
- Physician's Desk Reference.

See CACI §1222.

Claim 3: Breach of Warranty

1. That Mrs. Georges bought the Aredia or Zometa from NPC.

- Infusion records.

2. That, at the time of purchase, NPC was in the business of selling Aredia or Zometa;

- This fact is uncontested by Novartis.

3. That the Aredia or Zometa was not fit for the ordinary purposes for which such goods are used, were not adequately contained, packaged and labeled as the agreement may require or did not conform to the promises or affirmations of fact made on the container or label if any;

- Aredia and Zometa labels.
- Edge and Compass reports relating to Mrs. Georges.
- NPC advertising.
- Physician's Desk Reference.

4. That Mrs. Georges took reasonable steps to notify NPC within a reasonable time that the product did not have the expected quality;

- Mrs. Georges Complaint (*See* Exhibit 1177).
- Adverse event reports.

5. That Mrs. Georges was harmed; and

- Live Testimony of Mrs. Georges.
- Live testimony of Mr. Georges.
- Live testimony and expert report of Dr. Sung.
- Testimony of Dr. Waisman and other treating physicians.
- Mrs. Georges' medical records, and other documents and photographs produced by plaintiff. (*See* Exhibits 1116-1176, 1179, 1181).

6. That the failure of Aredia or Zometa to have the expected quality was a substantial factor in causing Mrs. Georges' harm.

- Live Testimony of Mrs. Georges.
- Live testimony of Mr. Georges.

- Live testimony and expert report of Dr. Sung.
- Live testimony of Robert Marx.

See CACI §1231; *see also* California Commercial Code Sec. 2314.

Claim 4: Fraudulent Concealment

1. That NPC concealed or suppressed a material fact;

- Live testimony of Robert Marx.
- Live testimony of Dr. Suzanne Parisian.
- Aredia and Zometa labels.
- Fratacangeli email regarding plan to suppress Ruggiero's article from ever seeing the light of day.
- Email from Dr. Ruggiero regarding ONJ cases.
- Email from Schubert regarding white paper.
- Email of Linda Weiss regarding alternate risk factors.
- Goessl email to NEM team regarding osteopetrosis.
- Document(s) evidencing cases of ONJ in the clinical trials.
- Dr. Marx's comments on white paper. (*See* Exhibits 1210, 1211).
- Tarassoff's response to Marx's letter to the editor. (*See* Exhibit 1029).
- In October of 2004, Dr. Waisman wrote in his chart for Mrs. Georges, "Her mandible lesion, I believe, may be osteonecrosis from Zometa." After speculating at the cause of Mrs. Georges jaw pain, in January of 2005, Dr. Waisman held Mrs. Georges Zometa infusions. When the topic of restarting bisphosphonate therapy arose again, Mrs. Georges refused to have the treatment. It is Dr. Waisman's belief that Zometa® was part of the cause of Mrs. Georges ONJ. (*See* Exhibit 227).
- NPC advertising.

2. That NPC was under a duty to disclose the fact to Mrs. Georges;

- Live testimony of Dr. Suzanne Parisian.
- NPC interactions with Drs. Marx and Ruggiero.

3. That NPC intentionally concealed or suppressed the fact with the intent to defraud Mrs. Georges;

- Fratarcangeli email regarding plan to suppress Ruggiero's article from ever seeing the light of day.
- Tarassoff's response to Marx's letter to the editor. (*See* Exhibit 1029).
- Email from Dr. Ruggiero regarding ONJ cases.
- Email from Schubert regarding white paper.
- Email of Linda Weiss regarding alternate risk factors.
- NPC interactions with Drs. Marx and Ruggiero.
- NPC advertising.

4. That Mrs. Georges was unaware of the fact and would not have acted as she did if she had known of the concealed or suppressed fact; and

- Live Testimony of Mrs. Georges.
- Live testimony of Mr. Georges.
- Testimony of Dr. Waisman and other treating physicians.

5. That as a result of the concealment or suppression of the fact, Mrs. Georges sustained damage.

- Live Testimony of Mrs. Georges.
- Live testimony of Mr. Georges.
- Live testimony and expert report of Dr. Sung.
- Testimony of Dr. Waisman and other treating physicians.
- Mrs. Georges' medical records, and other documents and photographs produced by plaintiff. (*See* Exhibits 1116-1176, 1179, 1181).

1
2 *See Jones v. ConocoPhillips Co.*, (2011) 198 Cal. App. 4th 1187, 1198.

3
4 DEFENDANT'S AFFIRMATIVE DEFENSES

5
6 (a) NPC plans to pursue the following affirmative defenses:⁵

7 Affirmative Defense 1: Comparative Negligence

8 Affirmative Defense 2: Plaintiff's Misuse/Abnormal Use of Product

9 Affirmative Defense 3: Failure to Mitigate Damages – Personal Injury

10 Affirmative Defense 4: Failure to Mitigate Damages – Past Lost Earnings

11 Affirmative Defense 5: Failure to Mitigate Damages – Future Lost Earnings

12 Affirmative Defense 6: Statute of Limitations

13
14 (b) The elements required to establish Defendant's affirmative defenses are:

15 **Affirmative Defense 1: Comparative Negligence**

16 (1) That [Ms. Georges or name of third party] was negligent; and

17 (2) That this negligence was a substantial factor in causing Ms. Georges' harm.⁶

18 Plaintiff objects to Defendant's assertion of Comparative Negligence as an

19
20 ⁵ The Local Rules expressly direct defendants to include discussion of only *affirmative*
21 defenses as part of the Final Pretrial Conference Order. *See* Local Rules for the Central
22 District of California, Appendix A, Pretrial Form No. 1, paragraph 7(a) (under heading
23 "Defendants") (December 1, 2012). Accordingly, NPC is not including discussion of the
24 many rules of law on which it intends to rely at trial that, even though they may sometimes
25 be referred to as "defenses," do not qualify as affirmative defenses under California law.
26 These include, for example only, the Learned Intermediary Doctrine, the Restatement 2d of
27 Torts § 402A, comments j and k, the Special Benefits Doctrine, and NPC's compliance with
28 FDA regulations. NPC does not discuss these rules of law herein because they are not
affirmative defenses. NPC does not waive application of any of these rules of law, and
expressly reserves the right to rely upon them at trial.

⁶ CACI Jury Instruction Nos. 406, 1207A, 1207B.

1 affirmative defense in its entirety. Under the circumstances in this case, this is an improper
2 use of this affirmative defense. Smoking simply does not cause BRONJ. As such, plaintiff
3 objects to this affirmative defense and any related instruction being given to the jury in this
4 case.

5
6 **Affirmative Defense 2: Plaintiff's Misuse/Abnormal Use of Product**

7 (1) That Ms. Georges negligently misused Aredia® or Zometa®; and

8 (2) That this negligence was a substantial factor in causing Ms. Georges' harm.⁷

9 Plaintiff objects to Defendant's assertion of Plaintiff's Misuse/Abnormal Use of
10 Product as an affirmative defense in its entirety. Under the circumstances in this case, this
11 is an improper use of this affirmative defense. As such, plaintiff objects to this affirmative
12 defense and any related instruction being given to the jury in this case.

13
14 **Affirmative Defense 3: Failure to Mitigate Damages – Personal Injury**

15 (1) That Ms. Georges suffered harm that Ms. Georges could have avoided with
16 reasonable efforts or expenditures.⁸

17 Plaintiff objects to Defendant's assertion of Failure to Mitigate Damages – Personal
18 Injury as an affirmative defense in its entirety. Under the circumstances in this case, this is
19 an improper use of this affirmative defense. As such, plaintiff objects to this affirmative
20 defense and any related instruction being given to the jury in this case.

21
22 **Affirmative Defense 4: Failure to Mitigate Damages – Past Lost Earnings**

23 (1) That Ms. Georges suffered economic losses that Ms. Georges could have
24 avoided by returning to gainful employment as soon as it was reasonable for

25
26
27 ⁷ CACI Jury Instruction No. 1207A.

28 ⁸ CACI Jury Instruction No. 3930.

her to do so.⁹

Affirmative Defense 5: Failure to Mitigate Damages – Future Lost Earnings

(1) That there are future economic losses that Ms. Georges will be able to avoid by returning to gainful employment as soon as it is reasonable for her to do so.¹⁰

Affirmative Defense 6: Statute of Limitations

(1) That Ms. Georges' claimed harm occurred before July 21, 2004.

If NPC proves element (1), then the burden shifts to Plaintiff to prove:

(2) That before July 21, 2004, Ms. Georges did not discover and did not know of facts that would have caused a reasonable person to suspect, that she had suffered harm that was caused by someone's wrongful conduct.

Or, alternatively, depending on the circumstances:

(3) That Ms. Georges did not discover, and a reasonable and diligent investigation would not have disclosed, that Aredia® and Zometa® contributed to Ms. Georges' harm.¹¹

(c) In brief, the key evidence Defendant relies on for each affirmative defense is:

Affirmative Defense 1: Comparative Negligence

(1) That [Ms. Georges or name of third party] was negligent: Mrs. Georges has smoked for over 40 years and continues smoke even after her jaw conditions developed. Smoking is known to contribute to disorders of the jaw including osteomyelitis, osteonecrosis of the jaw, and other infections.

⁹ CACI Jury Instruction No. 3961.

¹⁰ CACI Jury Instruction No. 3962.

¹¹ CACI Jury Instruction Nos. 454, 455; Cal. Code Civ. P. 335.1 (two year statute of limitations for personal injury actions).

1 Smoking is also known to inhibit healing. Ms. Georges also underwent tooth
2 extractions after she learned of the potential connection between her injuries
3 and her use of Zometa®, and after she learned that she should avoid tooth
4 extractions. Ms. Georges has repeatedly failed to comply with prescribed
5 dosage of antibiotics and her doctors' recommendations for other medications,
6 and has discontinued antibiotic prescriptions before they were complete,
7 increasing the risk of bacterial resistance. NPC will also rely upon additional
8 evidence of Ms. Georges' contributing negligence.

- 9 **(2) That this negligence was a substantial factor in causing Ms. Georges'**
10 **harm:** NPC will rely upon testimony of NPC's experts and Plaintiff's experts
11 to establish that the above negligence contributed to Ms. Georges' harm.
12

13 **Affirmative Defense 2: Plaintiff's Misuse/Abnormal Use of Product**

- 14 **(1) That Ms. Georges negligently misused Aredia® or Zometa®:** Ms. Georges
15 underwent tooth extractions after she learned of the potential connection
16 between her injuries and her use of Zometa®, and after she learned that she
17 should avoid tooth extractions. NPC will also rely upon additional evidence of
18 Ms. Georges' contributing negligence.

- 19 **(2) That this negligence was a substantial factor in causing Ms. Georges'**
20 **harm:** NPC will rely upon testimony of NPC's experts and Plaintiff's experts
21 to establish that the above negligence contributed to Ms. Georges' harm.
22

23 **Affirmative Defense 3: Failure to Mitigate Damages – Personal Injury**

- 24 **(1) That Ms. Georges suffered harm that Ms. Georges could have avoided**
25 **with reasonable efforts or expenditures:** Mrs. Georges has smoked for over
26 40 years and continues smoke even after her jaw conditions developed.
27 Smoking is known to contribute to disorders of the jaw including
28 osteomyelitis, osteonecrosis of the jaw, and other infections. Smoking is also

known to inhibit healing. Ms. Georges also underwent tooth extractions after she learned of the potential connection between her injuries and her use of Zometa®, and after she learned that she should avoid tooth extractions. Ms. Georges has repeatedly failed to comply with prescribed dosage of antibiotics and her doctors' recommendations for other medications, and has discontinued antibiotic prescriptions before they were complete, increasing the risk of bacterial resistance. NPC will also rely upon additional instances of Ms. Georges' failure to mitigate her personal injuries.

Affirmative Defense 4: Failure to Mitigate Damages – Past Lost Earnings

(1) That Ms. Georges suffered economic losses that Ms. Georges could have avoided by returning to gainful employment as soon as it was reasonable for her to do so: To the extent Ms. Georges continues to seek damages for past lost earnings, NPC will rely upon evidence from Ms. Georges' medical records, social security disability records, and deposition testimony, that she was not rendered unable to work as a result of her alleged injuries in this case; and that, therefore, from the perspective of her alleged injuries, she should have never withdrawn from gainful employment.

Affirmative Defense 5: Failure to Mitigate Damages – Future Lost Earnings

(1) That there are future economic losses that Ms. Georges will be able to avoid by returning to gainful employment as soon as it is reasonable for her to do so: To the extent Ms. Georges continues to seek damages for future lost earnings, NPC will rely upon evidence from Ms. Georges' medical records, social security disability records, and deposition testimony, that she has not been rendered unable to work as a result of her alleged injuries in this case; and that, therefore, from the perspective of her alleged injuries, she should not be withdrawn from gainful employment.

Affirmative Defense 6: Statute of Limitations

(1) That Ms. Georges' claimed harm occurred before July 21, 2004: NPC will rely on Ms. Georges' medical records, her own testimony, and the testimony of her providers that she developed exposed bone well before this date.

If NPC proves element (1), then the burden shifts to Plaintiff to prove:

(2) That before July 21, 2004, Ms. Georges did not discover and did not know of facts that would have caused a reasonable person to suspect, that she had suffered harm that was caused by someone's wrongful conduct: It is plaintiff's burden to satisfy this element.

Or, alternatively, depending on the circumstances:

(3) That Ms. Georges did not discover, and a reasonable and diligent investigation would not have disclosed, that Aredia® and Zometa® contributed to Ms. Georges' harm: It is plaintiff's burden to satisfy this element.

8. ISSUES REMAINING TO BE TRIED

In view of the admitted facts and the elements required to establish the claims, counterclaims and affirmative defenses, the following issues remain to be tried: [list ultimate issues, not evidentiary issues]:

Plaintiffs' claims

Claim 1: Product Liability – Strict Liability

1. Whether NPC manufactured, distributed or sold Aredia and Zometa;
2. Whether Aredia or Zometa had potential risks or side effects that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific community at the time of manufacture, distribution or sale;
3. Whether the potential risks or side effects presented a substantial danger when Aredia or Zometa are used or misused in an intended or reasonably foreseeable way;

1 4. Whether ordinary consumers would not have recognized the potential risks or
2 side effects;

3 5. Whether NPC failed to adequately warn or instruct of the potential risks or
4 side effects;

5 6. Whether Mrs. Georges was harmed;

6 7. Whether the lack of sufficient instructions or warnings was a substantial factor
7 in causing Mrs. Georges' harm;

8 8. Whether the warning was given to Mrs. Georges' prescribing physician and
9 included the potential risks, side effects, or allergic reactions that may follow the
10 foreseeable use of Aredia and Zometa. Whether NPC fulfilled its continuing duty to warn
11 physicians as long as the Aredia and Zometa were in use.

12 NPC objects to Plaintiff's characterization of the issues remaining to be tried with
13 regard to Claim 1: Product Liability – Strict Liability; and incorporates by reference the
14 language used in NPC's statement of the elements for this claim, provided in paragraph 7
15 above.

16
17 **Claim 2: Negligence – Negligent Manufacturing and Failure to Warn**

18 1. Whether NPC manufactured, distributed or sold Aredia and Zometa;

19 2. Whether NPC knew or reasonably should have known that Aredia or Zometa
20 were dangerous or were likely to be dangerous when used in a reasonably foreseeable
21 manner;

22 3. Whether NPC knew or reasonably should have known that users would not
23 realize the danger;

24 4. Whether NPC failed to adequately warn of the danger or instruct on the safe
25 use of Aredia or Zometa;

26 5. Whether a reasonable manufacturer, distributor or seller under the same or
27 similar circumstances would have warned of the danger or instructed on the safe use of
28 Aredia or Zometa;

6. Whether Mrs. Georges was harmed;

7. Whether NPC's failure to warn or instruct was a substantial factor in causing Mrs. Georges' harm; and

8. Whether a warning was given to Mrs. Georges' prescribing physician and must include the potential risks or side effects that may follow the foreseeable use of Aredia or Zometa. Whether NPC fulfilled its continuing duty to warn physicians as long as Aredia or Zometa were in use.

NPC objects to Plaintiff's characterization of the issues remaining to be tried with regard to Claim 2: Negligence – Negligent Manufacturing and Failure to Warn; and incorporates by reference the language used in NPC's statement of the elements for this claim, provided in paragraph 7 above.

Claim 3: Breach of Warranty

1. Whether Mrs. Georges bought the Aredia or Zometa from NPC.

2. Whether, at the time of purchase, NPC was in the business of selling Aredia or Zometa;

3. Whether the Aredia or Zometa was not fit for the ordinary purposes for which such goods are used, were not adequately contained, packaged and labeled as the agreement may require or did not conform to the promises or affirmations of fact made on the container or label if any;

4. Whether Mrs. Georges took reasonable steps to notify NPC within a reasonable time that the product did not have the expected quality;

5. Whether Mrs. Georges was harmed; and

6. Whether the failure of Aredia or Zometa to have the expected quality was a substantial factor in causing Mrs. Georges' harm.

NPC objects to Plaintiff's characterization of the issues remaining to be tried with regard to Claim 3: Breach of Warranty; and contends that there are no issues remaining to

1 be tried for this improper claim.

2
3
4 **Claim 4: Fraudulent Concealment**

- 5 1. Whether NPC concealed or suppressed a material fact;
6 2. Whether NPC was under a duty to disclose the fact to Mrs. Georges;
7 3. Whether NPC intentionally concealed or suppressed the fact with the intent to
8 defraud Mrs. Georges;
9 4. Whether Mrs. Georges was unaware of the fact and would not have acted as
10 she did if she had known of the concealed or suppressed fact; and
11 5. Whether, as a result of the concealment or suppression of the fact, Mrs.
12 Georges sustained damage.

13 NPC objects to Plaintiff's characterization of the issues remaining to be tried with
14 regard to Claim 4: Fraudulent Concealment; and incorporates by reference the language
15 used in NPC's statement of the elements for this claim, provided in paragraph 7 above.

16
17
18 **Defendant's counterclaims**¹²

19 In view of the admitted facts and the elements required to establish the affirmative
20 defenses, the following issues remain to be tried:

21 **Affirmative Defense 1: Comparative Negligence**

- 22 (1) Whether [Ms. Georges or name of third party] was negligent; and
23 (2) Whether this negligence was a substantial factor in causing Ms. Georges'
24 harm.

25
26 ¹² Plaintiff objects to NPC's characterization of the issues remaining to be tried with regard
27 to its affirmative defenses, and incorporates by reference the plaintiff's objections provided
28 in paragraph 7 above.

Affirmative Defense 2: Plaintiff's Misuse/Abnormal Use of Product

- (1) Whether Ms. Georges negligently misused Aredia® or Zometa®; and
- (2) Whether this negligence was a substantial factor in causing Ms. Georges' harm.

Affirmative Defense 3: Failure to Mitigate Damages – Personal Injury

- (1) Whether Ms. Georges suffered harm that Ms. Georges could have avoided with reasonable efforts or expenditures.

Affirmative Defense 4: Failure to Mitigate Damages – Past Lost Earnings

- (1) Whether Ms. Georges suffered economic losses that Ms. Georges could have avoided by returning to gainful employment as soon as it was reasonable for her to do so.

Affirmative Defense 5: Failure to Mitigate Damages – Future Lost Earnings

- (1) Whether there are future economic losses that Ms. Georges will be able to avoid by returning to gainful employment as soon as it is reasonable for her to do so.

Affirmative Defense 6: Statute of Limitations

- (1) Whether Ms. Georges' claimed harm occurred before July 21, 2004; and
- (2) Whether before July 21, 2004, Ms. Georges did not discover and did not know of facts that would have caused a reasonable person to suspect, that she had suffered harm that was caused by someone's wrongful conduct.

Or, alternatively, depending on the circumstances:

- (3) Whether Ms. Georges did not discover, and a reasonable and diligent investigation would not have disclosed, that Aredia® and Zometa® contributed to Ms. Georges' harm.

9. DISCOVERY

All discovery is complete.

1 **10. DISCLOSURES**

2 All disclosures under Fed. R. Civ. P. 26(a)(3) have been made.

3 The joint exhibit list of the parties has been filed under separate cover as required by
4 L.R. 16-6.1. Unless all parties agree that an exhibit shall be withdrawn, all exhibits will be
5 admitted without objection at trial, except those exhibits listed below:¹³

6 See Pretrial Exhibit Stipulation, filed concurrently herewith.

7
8 **11. WITNESS LISTS**

9 Witness lists of the parties have been filed with the Court.

10 Only the witnesses identified in the lists will be permitted to testify (other than
11 solely for impeachment).

12 Plaintiff respectfully requests that the following witnesses be added to Plaintiff's
13 exhibit list:

- 14 ○ Dianne Young
- 15 ○ Joanne Machalaba
- 16 ○ Carsten Goessl
- 17 ○ Yong Hei

18 Plaintiff has already included the testimony of these witnesses in her deposition
19 designations, but in an abundance of caution, would like to add them to her exhibit list so
20 that they may be called as live witnesses.

21 NPC objects to Plaintiff's late attempts to amend the Witness List, and objects to
22 any attempts by Plaintiff to require NPC to produce live company witnesses who do not
23 reside within this jurisdiction, and who are not within the subpoena power of this Court.

24 Each party intending to present evidence by way of deposition testimony has marked
25

26 ¹³ Many of the parties' exhibits pertain to issues that are the subject of one or more pending
27 motions *in limine*. The parties reserves the right to unilaterally withdraw such exhibits from
28 their exhibit lists to the extent they pertain to matters that are rendered irrelevant or
otherwise inadmissible as a result of the Court's decisions on the pending motions.

1 such depositions in accordance with L.R. 16-2.7. For this purpose, the following
2 depositions shall be lodged with the Clerk as required by L.R. 32-1:

3 Virtually all depositions as played at trial in *Kyle v. Novartis Pharms. Corp.* – a case
4 whose plaintiff was also a breast cancer patient and had similar timing of infusions.
5 Plaintiff has only designated the first deposition of Goessl (taken in 2008) in the instant
6 designation and objects to Goessl's second depositions (taken in 2010) being played in this
7 trial. A listing of plaintiff's specific depositions and clips are attached hereto as **Exhibit A**.
8

9 Defendant objects to the presentation of testimony by deposition of the following
10 witnesses:

11 NPC agrees to the presentation of the deposition designations played at trial in *Kyle*
12 *v. Novartis Pharms. Corp.*, subject only to the Court's rulings on the parties' pending
13 motions *in limine*. NPC reserves the right to play deposition testimony from the 2010
14 deposition of Carsten Goessl, as it was played in the trial of *Kyle v. Novartis Pharms.*
15 *Corp.*, at the same time the other deposition testimony from Mr. Goessl is played.
16

17 **12. LAW AND MOTION/MOTIONS IN LIMINE**

18 The following law and motion matters and motions in limine, and no others, are
19 pending or contemplated:

20 Plaintiff's Motions in Limine

21 Plaintiff has filed two motions *in limine*:

- 22 • Plaintiff's Omnibus Motion in Limine No.1 to Exclude Various Evidence (Dkt. No.
23 161).
- 24 • Plaintiff's Motion in Limine No. 2 to Exclude Evidence Which Expands the Use or
25 Efficacy of Aredia or Zometa Beyond the Approved Indications at the Time
26 Plaintiff Received the Drug (Dkt. No. 162).

27 Defendant's Motions in Limine

28

Defendant has filed eight motions *in limine*, including:

- Defendant Novartis Pharmaceuticals Motion in Limine [No. 1] to Exclude Evidence or Argument Suggesting a Duty to Warn Dental Providers (Dkt. No. 197);
- Defendant Novartis Pharmaceuticals Motion in Limine [No. 2] to Exclude Certain Causation Testimony and Evidence From Plaintiff's Treating Physicians (Dkt. No. 191);
- Defendant Novartis Pharmaceuticals Omnibus Motion in Limine [No. 5] (Dkt. No. 198);
- Defendant Novartis Pharmaceuticals Motion in Limine [No. 6] to Exclude Evidence of NPC's Knowledge/Conduct Following Ms. Georges' Bisphosphonate Treatment (Dkt. No. 192);
- Defendant Novartis Pharmaceuticals Motion in Limine [No. 13] to Exclude Labeling and Dosing Issues Controlled by FDA (Dkt. No. 193);
- Defendant Novartis Pharmaceuticals Motion in Limine [No. 14] to Exclude Certain Inadmissible Testimony by Dr. James Vogel (Dkt. No. 194);
- Defendant Novartis Pharmaceuticals Motion in Limine [No. 15] to Exclude Certain Inadmissible Testimony by Professor Wayne Ray (Dkt. No. 195);
- Defendant Novartis Pharmaceuticals Motion in Limine [No. 16] to Exclude Testimony by Dr. Eric Sung Regarding the Incidence of ONJ (Dkt. No. 196)

In addition to these pending Motions, Defendant contemplates filing a Motion for Judgment as a Matter of Law, pursuant to Fed. R. Civ. P. 50(a), at the close of Plaintiff's evidence.

13. BIFURCATION

Bifurcation of the following issues for trial is ordered:

None.

1 **14. EFFECT OF FINAL PRETRIAL CONFERENCE ORDER**

2 The foregoing admissions having been made by the parties, and the parties having
3 specified the foregoing issues remaining to be litigated, this Final Pretrial Conference
4 Order shall supersede the pleadings and govern the course of the trial of this cause, unless
5 modified to prevent manifest injustice.

6
7
8 Dated March 11, 2013

HON. S. JAMES OTERO
UNITED STATES DISTRICT JUDGE

9
10
11 Approved as to form and content.

12 GIRARDI | KEESE

13
14 /s/ John A. Girardi

John A. Girardi

15 *Attorney for Plaintiff*

16
17 PARKER, MILLIKEN, CLARK
18 O'HARA & SAMUELIAN, APC

19 /s/ Natasha N. Dawood

Natasha N. Dawood

20 *Attorney for Defendant*